UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

PIO ZAMMIT,

Plaintiff,

v.

Case No. 05-70247
Hon. Gerald E. Rosen

SHIRE US, INC.,

Defendant.
_____/

OPINION AND ORDER GRANTING
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

At a session of said Court, held in
the U.S. Courthouse, Detroit, Michigan
on 2/16/06

PRESENT: Honorable Gerald E. Rosen
United States District Judge

I. INTRODUCTION

Plaintiff Pio Zammit, proceeding *pro se*, commenced this suit in this Court on January 24, 2005, asserting product liability claims against Defendant Shire US, Inc., the manufacturer of the pharmaceutical products Adderall and Adderall XR. In support of these claims, Plaintiff alleges that he was prescribed and began taking Adderall in April of 2002, and that his use of this product led to a heart attack and heart damage on April 24, 2002. This Court's subject matter jurisdiction rests upon diversity of citizenship, as Plaintiff is a Michigan resident and Defendant evidently is a Pennsylvania corporation. See 28 U.S.C. § 1332(a).

By motion filed on July 5, 2005, Defendant now seeks summary judgment in its favor. As observed by Defendant, Plaintiff's product liability claims in this diversity suit are governed by Michigan law. In a 1995 enactment, the Michigan legislature conferred broad immunity upon drug manufacturers in product liability suits, shielding them from liability, with certain limited exceptions, if the drug in question "was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer." Mich. Comp. Laws § 600.2946(5). In support of its present motion, Defendant argues that Plaintiff's product liability claims in this action are defeated by the immunity granted under this Michigan statute, where Defendant secured the approval of the federal Food and Drug Administration ("FDA") for the sale of its Adderall and Adderall XR products.

Having reviewed Defendant's motion, Plaintiff's responsive submissions,[1] and the remainder of the record, the Court finds that the relevant allegations, facts, and legal arguments are adequately presented in these materials, so that oral argument would not significantly aid the decisional process. Accordingly, the Court will decide Defendant's motion "on the briefs." See Local Rule 7.1(e)(2), U.S. District Court, Eastern District of

[1]Although Plaintiff's submissions to this Court have been both numerous and voluminous, none of them is specifically captioned as a response to Defendant's summary judgment motion. Perhaps the most likely candidate for such a submission is Plaintiff's July 11, 2005 motion for summary judgment, as supplemented on numerous occasions, which addresses at least some of the arguments advanced in Defendant's motion. In any event, the Court has carefully reviewed each of Plaintiff's many submissions in an effort to identify any points he has raised in response to the contentions in Defendant's motion.

Michigan. For the reasons set forth below, the Court readily concludes that Defendant is entitled to summary judgment, as Plaintiff's various challenges to Michigan's statutory scheme governing product liability suits have been rejected in Michigan Supreme Court and Sixth Circuit Court of Appeals rulings that are binding upon this Court.

II. FACTUAL AND PROCEDURAL BACKGROUND

As Defendant has repeatedly observed in its filings throughout this case, Plaintiff's many submissions to this Court typically are accompanied by sheaves of materials that the Court may not consider, particularly in resolving a motion for summary judgment. See Fed. R. Civ. P. 56(c), (e); see also U.S. Structures, Inc. v. J.P. Structures, Inc., 130 F.3d 1185, 1189 (6th Cir. 1997) (explaining that "evidence submitted in opposition to a motion for summary judgment must be admissible"). Accordingly, the following recitation of facts is derived largely from the allegations of Plaintiff's complaint, as supplemented by certain of the exhibits accompanying Defendant's motion.

A. The Allegations in Support of Plaintiff's Product Liability Claims

According to the complaint, Plaintiff Pio Zammit was given a prescription for Adderall on April 5, 2002, and began taking this medication that same day.[2] Plaintiff alleges that the use of this product caused him to experience a pounding heartbeat, tightness in his chest, palpitations, and nausea. Accordingly, Plaintiff decided to

[2]As noted by Defendant, the record appears to suggest that Plaintiff actually was prescribed the drug Adderall XR, and not Adderall. For the reasons indicated below, however, this factual discrepancy does not alter the Court's analysis of the present motion.

discontinue the use of this product after a few days.

A short while later, on April 24, 2002, Plaintiff suffered a heart attack as he was leaving his doctor's office. He was rushed to an emergency room and treated, but Plaintiff alleges that this episode caused permanent damage to his heart, and that his use of Adderall has resulted in continuing complications to his overall health.

B. The FDA Approval of Defendant's Adderall and Adderall XR Products

Defendant Shire US, Inc. is a pharmaceutical manufacturer. The company manufactures and markets the medications at issue here, Adderall and Adderall XR, for treatment of attention deficit hyperactivity disorder ("ADHD") and narcolepsy. Both of these products are amphetamine-based.

Defendant's Adderall product dates back to the 1960s, and was first released in its current formulation in 1973 under the name of Obetrol. Defendant's predecessor in interest, Rexar, secured the approval of the U.S. Food and Drug Administration ("FDA") for this product and its labeling in the late 1970s, and the FDA again approved this product for manufacture and marketing in 1996. In 1997, Defendant acquired the rights to this product through a series of mergers and acquisitions, and the product's name was changed to Adderall during this same time period.

In October of 2000, Defendant filed a New Drug Application with the FDA, seeking approval of an extended-release formulation of Adderall to be marketed under the

name Adderall XR.[3] Following an exchange of correspondence between Defendant and the FDA regarding the labeling of this product, the FDA approved Adderall XR for the treatment of ADHD on October 1, 2001.

C. Procedural Background

Plaintiff commenced this suit in January of 2005, just under three years after his use of Defendant's Adderall or Adderall XR product in April of 2002. At a March 28, 2005 scheduling conference, and again in a May 4, 2005 order, the Court urged Plaintiff to retain counsel to assist him, but he continues to proceed *pro se* in this litigation.

The discovery process in this action has not gone smoothly. First, Plaintiff has sought on several occasions to use this case as a vehicle for submitting Freedom of Information Act ("FOIA") requests to the FDA (as well as the private Defendant), and for seeking to compel this non-party federal agency to change the labeling on Defendant's products. As explained in the Court's May 4 and May 11, 2005 orders, however, Plaintiff has not identified any basis for joining the FDA as a party to this suit or otherwise ordering this non-party to take any particular action. Neither has Plaintiff suggested any jurisdictional ground for the Court to address his FOIA requests within the scope of this product liability suit. Rather, any possible remedies against the FDA must be sought, at least initially, through the administrative and FOIA-based mechanisms cited in the

[3]Again, it appears that this is the product prescribed to and used by Plaintiff.

Court's prior orders.[4]

Plaintiff's efforts to obtain discovery from Defendant have been equally problematic. As recounted at length in Defendant's present motion, the company sought Plaintiff's concurrence in a protective order before it would agree to produce documents, but Plaintiff was reluctant to execute such an agreement. When Defendant then proposed a limited opportunity for inspection without such a protective order, Plaintiff again refused, and instead suggested that Defendant could produce its documents for *in camera* inspection and review by the Court. Plainly, however, it would violate this Court's role as a neutral arbiter to sift through the record in an effort to identify evidentiary support for one party's position versus another.

At the end of the day, then, Plaintiff has marshaled little or no evidence that could be used to oppose Defendant's present request for summary judgment in its favor. Yet, in light of the Michigan statutory scheme that governs product liability claims against drug manufacturers, it is not evident that a more productive discovery effort would have affected the outcome here. Accordingly, the Court turns to this matter.

III. ANALYSIS

A. The Standards Governing Defendant's Motion

Through its present motion, Defendant seeks an award of summary judgment in its

[4]Moreover, as discussed below, Plaintiff's efforts to obtain information from the FDA and to compel the agency to take action on Defendant's products have no bearing upon the proper disposition of this case.

favor on Plaintiff's product liability claims. Under the pertinent Federal Rule, summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

The parties agree that Plaintiff's claims in this diversity action are governed by Michigan law. As discussed below, the record is clear and undisputed as to the facts that bear upon the proper disposition of these claims, leaving only questions of law to be decided by the Court.

B. Under Michigan's Product Liability Statute, Defendant Is Immune from Liability in This Case.

In his *pro se* complaint in this case, Plaintiff alleges that the Defendant drug manufacturer negligently failed to provide him with an adequate warning that its Adderall product could cause damage to his heart. Through the present motion, Defendant argues that this theory of product liability is foreclosed by a Michigan statute, Mich. Comp. Laws § 600.2946(5), which accords conclusive weight to the FDA's approval of a drug and its labeling. The Court agrees.

All are agreed that Michigan law governs this diversity action. See Garcia v. Wyeth-Ayerst Laboratories, 385 F.3d 961, 963 (6th Cir. 2004). In particular, Defendant's motion rests upon a provision of Michigan's product liability statute that confers broad immunity upon pharmaceutical companies in cases where the drug at issue has been

approved for sale by the FDA:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> > (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, . . . and the drug would not have been approved or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.
> >
> > (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

Mich. Comp. Laws § 600.2946(5) (citations omitted).

As recently observed by the Michigan Supreme Court, a predecessor statute "provided that evidence showing compliance with governmental or industry standards was admissible in a products liability action in determining if the standard of care had been met." Taylor v. Smithkline Beecham Corp., 468 Mich. 1, 658 N.W.2d 127, 130 (2003) (citations omitted). The above-cited 1995 enactment "went one step further," however, "and provided that compliance with federal governmental standards (established

by the FDA) is conclusive on the issue of due care for drugs." Taylor, 658 N.W.2d at 130.

Under the plain language of this statute, the Defendant drug manufacturer in this case is exempt from liability, unless one of the two statutory exceptions to this immunity applies. The undisputed record shows that both of the products at issue here, Adderall and Adderall XR, were approved for manufacture and sale by the FDA, and that these approvals remained in effect during the time of Plaintiff's use of these drugs. It also is undisputed that these drugs and their labeling were in compliance with the FDA's approval at the time they left Defendant's control and became available for Plaintiff's use. Consequently, the governing Michigan statute provides that these two products were "not defective or unreasonably dangerous," and that Defendant "is not liable" in a product liability suit, Mich. Comp. Laws § 600.2946(5) — subject, of course, to the two above-cited statutory exceptions.

Before considering the applicability of these exceptions, however, the Court first must address Plaintiff's threshold constitutional challenge to the Michigan statute. Citing principles of due process and separation of powers, as well as the nondelegation doctrine, Plaintiff argues that the application of the Michigan statute to thwart his product liability claims would violate the state and federal constitutions. Yet, precisely the same constitutional challenges have been addressed, and rejected, in decisions that this Court is bound to follow.

First, in Taylor, supra, the Michigan Supreme Court addressed the contention that § 600.2946(5) violates the Michigan constitution by improperly delegating legislative authority to a federal agency, the FDA. The Court disagreed, reasoning that the statute's incorporation of the FDA's findings was legally indistinguishable from a statutory reference to other standards, such as weight or time of day, that are determined by federal agencies such as the National Bureau of Standards. See Taylor, 658 N.W.2d at 132-34. So long as such a standard has "independent significance" — meaning that "the agency or outside body making the finding is doing it for purposes independent from the particular statute that refers to it" — the Michigan Legislature does not improperly delegate its authority to the outside agency. Taylor, 658 N.W.2d at 136. This Court is bound by this ruling on a question of Michigan law by Michigan's highest court. See Garden City Osteopathic Hospital v. HBE Corp., 55 F.3d 1126, 1130 (6th Cir. 1995).[5]

Similarly, Plaintiff's federal constitutional challenges are defeated by a binding decision of the Sixth Circuit Court of Appeals. In Garcia v. Wyeth-Ayerst Laboratories, 265 F. Supp.2d 825 (E.D. Mich. 2003), Judge Lawson of this District addressed federal constitutional challenges to § 600.2946(5) in a case where a pain medication manufactured by the defendant pharmaceutical company destroyed the plaintiff's liver. Apart from advancing a question of federal preemption, discussed below, the plaintiff

[5]While Plaintiff repeatedly cites to Justice Kelly's dissent in Taylor, this Court is not at liberty to favor a dissenting view over a majority ruling of the Michigan Supreme Court on a matter of Michigan law.

argued that "the limits imposed by [the Michigan statute] on her ability to recover damages caused by drug manufacturers' products are so severe that her rights of access to the courts and to a jury trial [we]re abridged." Garcia, 265 F. Supp.2d at 833. The court disagreed, reasoning that the enactment of a state statute that "stiffens the standard of proof of a common law claim" is not tantamount to an outright deprivation of the right of access to the courts. 265 F. Supp.2d at 833-34. The court also rejected the plaintiff's due process challenges, explaining that "due process does not prohibit the abolition of causes of action by a state legislature because a person has no . . . vested interest . . . in any rule of the common law," and further finding that § 600.2946(5) survived scrutiny under the "rational basis" test that governs substantive due process claims. 265 F. Supp.2d at 834-35 (internal quotation marks and citations omitted).

On appeal, the Sixth Circuit affirmed these rulings. See Garcia, 385 F.3d at 967-68. Regarding the plaintiff's claim that § 600.2946(5) abridged her right of access to the courts, the Sixth Circuit found it "unnecessary to add anything to the thoughtful analysis provided by the district court on this question." Garcia, 385 F.3d at 967. The Court further agreed with the district court that the plaintiff's procedural and substantive due process challenges to the Michigan statute lacked merit, in light of the absence of a vested property right in a cause of action that has not yet accrued, and in light of the Court's determination that the statute "rationally furthers a legitimate state objective." Garcia, 385 F.3d at 968. Just as the Michigan Supreme Court's ruling in Taylor is binding upon this Court as an exposition of Michigan law, this Court also is bound to follow the Sixth

Circuit's decision in Garcia on matters of federal law. It follows that Plaintiff's state and federal constitutional challenges to § 600.2946(5) cannot succeed.

In light of these binding precedents, the Court is left only to consider whether Plaintiff might be able to successfully appeal to one of the statutory exceptions to the immunity otherwise conferred upon drug manufacturers under § 600.2946(5). Plaintiff has neither alleged nor produced evidence that Defendant made an illegal payment to an FDA official for the purpose of securing or maintaining the agency's approval of its Adderall products. He does seek to raise a question, however, as to whether Defendant withheld information from or made misrepresentations to the FDA in the process of seeking the agency's approval of its medications. In particular, Plaintiff evidently means to suggest that Defendant failed to fully disclose to the FDA all of the adverse effects suffered by users of Adderall and Adderall XR, which purportedly included a number of strokes and sudden deaths.[6]

---

[6]As his principal support for this contention, Plaintiff points to a number of articles he discovered on the Internet discussing the circumstances surrounding the February 9, 2005 decision by Health Canada, the Canadian counterpart to the FDA, to suspend the sale of Adderall XR on the Canadian market. In one of these articles, a Health Canada official is quoted as stating that Defendant's application for Canadian approval of Adderall XR did not include information about sudden deaths associated with the use of this product, and that this information "should have been part of" the manufacturer's application. Laura Eggertson, *US Senator Alleges FDA Tried to Prevent Adderall XR Withdrawal in Canada*, Canadian Medical Association Journal Mar. 29, 2005, *available at* http://www.cmaj.ca/cgi/content/full/172/7/865.

The evidentiary value of these submissions is quite limited, however. First, the statements of Health Canada officials as reported in these articles are inadmissible hearsay that the Court cannot consider in resolving Defendant's summary judgment motion. See U.S. Structures, supra, 130 F.3d at 1189. Next, any purported deficiencies in Defendant's application for Canadian approval of Adderall XR have little or no bearing upon the thoroughness and

Once again, the Court finds that this proposed avenue of proof is foreclosed by the Sixth Circuit's ruling in Garcia. Citing the U.S. Supreme Court's decision in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S. Ct. 1012 (2001), the district court in Garcia found that § 600.2946(5) was impliedly preempted by federal law to the extent that it invites judicial inquiry, in the context of a private product liability action, into the question whether a drug manufacturer committed fraud on the FDA in securing the agency's approval of a drug. See Garcia, 265 F. Supp.2d at 830-33.

The Sixth Circuit agreed, and then turned to the question of how the Michigan statute should be construed in light of this federal preemption:

> It is one thing . . . to say that *Buckman* applies to the [fraud on the FDA and bribery] exemptions contained in Michigan Compiled Laws § 600.2946(5); it is quite another to say that *Buckman* preempts these exemptions in all of their applications. Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of *state court* findings of fraud on the FDA. Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman*. But the same

---

accuracy of Defendant's application for FDA approval. Indeed, it is not clear whether, or to what extent, the information that allegedly was omitted from Defendant's Canadian application in 2003 and early 2004 would have been available when Defendant submitted its application for FDA approval in late 2000 and 2001. In any event, for what it is worth, the Court notes that Health Canada announced on August 24, 2005 that Defendant would be permitted to resume sales of Adderall XR on the Canadian market. See Health Canada August 24, 2005 News Release, *available at* http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2005/2005_92_e.html.

Under Michigan's product liability statute, of course, only the FDA approval process has any legal significance, and it is simply irrelevant whether some other government might have declined to authorize the sale of a drug in some other country, or whether the manufacturer's submission seeking such approval might have been deemed insufficient in some respect. Moreover, as discussed below, even the circumstances surrounding the ***FDA's*** approval of a drug cannot be litigated in the course of a private product liability suit brought under Michigan law, because such issues are preempted by federal law.

> concerns do not arise when the *FDA itself* determines that a fraud has been committed on the agency during the regulatory-approval process. Thus, in this setting, it makes abundant sense to allow a State that chooses to incorporate a federal standard into its law of torts to allow that standard to apply when the federal agency itself determines that fraud marred the regulatory-approval process. In the final analysis, the exemptions are invalid as applied in some settings (*e.g.*, when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (*e.g.* claims based on federal findings of bribery or fraud on the FDA).

Garcia, 385 F.3d at 966 (citation omitted). The Court then concluded that the Michigan Legislature would prefer this construction of § 600.2946(5) over an outright invalidation of the statute on grounds of federal preemption. See Garcia, 385 F.3d at 966-67.

In light of Garcia, this Court's inquiry is at an end. Plaintiff has neither alleged nor produced any evidence that the FDA itself has found any fault with Defendant's conduct or submissions during the course of the company's applications for agency approval of its Adderall and Adderall XR products. To the contrary, Plaintiff repeatedly and strenuously protests that the FDA ***should have*** rejected Defendant's applications or insisted upon additional warnings, rather than approving the applications and maintaining this position despite a different course of action by Canadian health officials. The Sixth Circuit's construction of § 600.2946(5), however, precludes this Court from embarking upon any independent inquiry into any purported deficiencies or fraud in Defendant's submissions to the FDA.[7] Because the FDA itself has made no such findings of

[7]And, needless to say, there is no jurisdictional basis in this case for any judicial inquiry into the wisdom of the FDA's decision to grant the approvals sought by Defendant. Rather, as the Court noted in earlier orders in this case, a wholly separate statutory scheme governs such challenges to the agency's drug determinations.

deficiencies or fraud, Plaintiff cannot invoke the "fraud on the FDA" exception to the immunity enjoyed by Defendant under Michigan's product liability statute.[8]

IV. CONCLUSION

For the reasons set forth above,

NOW, THEREFORE, IT IS HEREBY ORDERED that Defendant's July 5, 2005 Motion for Summary Judgment is GRANTED. In light of this ruling, IT IS FURTHER ORDERED that Plaintiff's July 11, 2005 Motion for Summary Judgment, as supplemented by several subsequent filings, is DENIED. IT IS FURTHER ORDERED that all other pending motions are DENIED AS MOOT.

s/Gerald E. Rosen
Gerald E. Rosen
United States District Judge

Dated: February 16, 2006

I hereby certify that a copy of the foregoing document was served upon counsel of record on February 16, 2006, by electronic and/or ordinary mail.

s/LaShawn R. Saulsberry
Case Manager

[8]Given the Court's ruling that Defendant is entitled to summary judgment in its favor on Plaintiff's product liability claims, it readily follows that Plaintiff's cross-motion for summary judgment must be denied. In addition, the remaining motions filed by the parties are now moot.